



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

7 9 8 4 '00 FEB -8 P1:59

FEB -2 2000

Ms. Eleanor F. Barbo
Senior Director
Regulatory Affairs
Whitehall-Robins Healthcare
Five Giralda Farms
Madison, New Jersey 07940-0851

Dear Ms. Barbo:

This is in response to your letter of January 19, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Whitehall-Robins Healthcare is making the following claim, among others, for the product **Centrum Focused Formulas Heart:**

“Helps maintain ...normal cholesterol levels...”

“Help your body maintain normal cholesterol levels”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease, namely hypercholesterolemia. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

978-0163

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret, Ph.D.
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, New Jersey District Office, Office of Compliance, HFR-MA340

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (r/f, file)
HFS-450 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Dorsey, Barnett, Nickerson)
f/t:HFS-456:rjm:2/1/00:docname:68967.adv:disc44



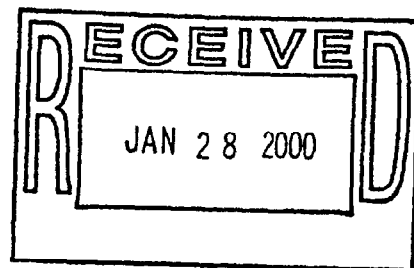
Whitehall-Robins
Five Giralda Farms
Madison, NJ 07940-0871
Telephone (973) 660-5500
Website address: <http://healthfront.com>

January 19, 2000

Centrum® Focused Formulas™ Heart

Notification of Statements on Dietary Supplement Labels

Elizabeth A. Yetley, Ph.D., R.D., Director
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204



Dear Dr. Yetley:

Reference is made to Centrum Focused Formulas, marketed by Whitehall-Robins Healthcare, ("Whitehall-Robins"), a division of American Home Products Corporation.

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. §343(r)(6), notification is submitted for structure/function statements made on the following dietary supplement product.

Product Name:	Centrum Focused Formulas Heart
Ingredients:	Vitamin E, Vitamin B6, Folic Acid, Vitamin B12, Selenium, Manganese, Garlic Powder , Taurine, Coenzyme Q10
Company Name/ Address:	Whitehall-Robins Healthcare Five Giralda Farms Madison, NJ 07940-0871

Statements on the Carton Label:

1. Front Panel/Top Flap

- A blend of select nutrients for a specific health need*
- Helps maintain healthy blood pressure, normal cholesterol levels, and homocysteine levels*

2. Back Panel

Centrum developed this advanced formula using ingredients which may:

- Help control low density lipoprotein (LDL) oxidation*
- Help your body maintain normal cholesterol levels*
- Help maintain cardiovascular health*

What are Centrum Focused Formulas?

- Centrum Focused Formulas are advanced combinations of vitamins, minerals, herbals, or other nutrients shown in scientific research to support a specific health area. *
- Centrum Focused Formulas are designed to provide nutritional solutions to help you better address your specific health needs. *

In accord with 21 CFR §101.93, the disclaimer statement is bolded and boxed on all panels of the carton label where structure/function claims appear.

The undersigned certifies that the information contained in this notice is complete and accurate, and that Whitehall-Robins has substantiation that the statements made are truthful and not misleading.

As required, the original and two copies of this notification are enclosed. If you have any questions regarding this information, please contact the undersigned at (973) 660-5751.

Sincerely,

WHITEHALL-ROBINS HEALTHCARE



Eleanor F. Barbo
Senior Director
Regulatory Affairs